

**From:** Vandenberg, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCAE2B98A04540FB8D099F9D4DEAD690-VANDENBERG, JOHN]  
**Sent:** 4/23/2014 12:54:49 PM  
**To:** Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Bradbury, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f19a4d59ea094b6e954047fc3d20632a-Steven P Bradbury]; Berner, Ted [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1949c9653024d3cb4aa4c2bd69c4fde-Berner, Ted]; Walsh, Debra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4fd965338fc4d449c2954945c41de46-Walsh, Debra]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Gatchett, Annette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f12d699a71f84e21bddbb876dae7f96c-Gatchett, Annette]  
**Subject:** FW: problem formulation

FYI – underscores need to collect info upfront to identify and seek to link to/address the risk mgmt context.

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**From:** Kavlock, Robert  
**Sent:** Monday, April 21, 2014 1:01 PM  
**To:** Vandenberg, John  
**Subject:** problem formulation

John- am sure you have seen this, but it does point to what I mentioned about highlighting problem formulation in assessments.

Bob

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## EPA Issues Risk Assessment Framework

Posted: April 18, 2014

EPA has issued its long-awaited framework aimed at strengthening the agency's human health risk assessments, a document that was recommended by a 2009 National Academy of Sciences (NAS) report to design the assessments to best inform agency decisionmaking.

The "Framework for Human Health Risk Assessment to Inform Decision Making," released April 15, is expected to be the first in a series of responses to "Science and Decisions: Advancing Risk Assessment," the NAS report on improving agency risk assessment practices.

Officials have long struggled to craft documents recommended by the NAS panel. But the effort has gained ground in recent months since the chairman of the committee that wrote the report, Johns

Hopkins University Associate Dean Thomas Burke, is awaiting Senate confirmation to lead EPA's research office.

In a 2009 interview shortly after the release of the NAS report, Burke said the report's focus is on breaking the logjams that often occur in risk assessment as agency assessors and others seek more information to reduce uncertainties in the analyses, which delays decisionmaking.

In addition to better planning and scoping of risk assessments, the NAS report called for consideration of what risk management options are available before starting an assessment so that its analyses are most relevant to the questions and risk management decisions at issue.

The new framework seeks to address those concerns by emphasizing the importance of planning, peer review, public and stakeholder input and community involvement in the risk assessment process, as well as the need to provide a clear explanation of the factors that led to a decision.

"[A]lthough the Agency is committed to advancing risk assessment science, assessments are not academic exercises," the framework document says. "Instead, they are intended to support decision making for the protection of human health. Application of the Framework, with its emphasis on problem formulation and the utility of the risk assessment, ultimately will result in better, more transparent choices among risk management options."

In addition to the core components of risk assessment, exposure and hazard assessments, the framework defines other key aspects as planning and scoping, problem formulation, stakeholder outreach and community involvement, and an explanation of how the various factors informed the final decision.

"Overall, the Framework stresses the practical nature of risk assessment; it highlights the need for analysis in support of decision making and additionally recognizes areas of overarching Agency interest, including children's environmental health and environmental justice," the framework says.

The framework also represents the first document that EPA's Risk Assessment Forum (RAF) has published since July 2012. The RAF, a standing body of senior agency scientists, nominated by their individual labs, offices and regions, creates agency-wide guides on risk assessment issues.

The Forum released no new documents in 2013, the first time in 23 years that has occurred. Sources suggested that Science Advisor Glenn Paulson, whom former Administrator Lisa Jackson appointed to the position in the spring of 2012, was the reason for the limited productivity. As Science Advisor, Paulson is the chairman of the agency's Science Technology and Policy Council (STPC), which oversees approval and release of RAF documents.

The new framework was one a handful of RAF documents that underwent peer review in the past several years but until recently remained stuck in editing and review processes. The framework does not provide new policy, but is instead expected to knit together existing EPA policies on risk assessment while focusing on increasing the utility of the practice by planning and scoping them around EPA's risk management needs. The document also states that it is intended to be sufficiently flexible to accommodate future guidance.

Robert Kavlock  
Deputy Assistant Administrator for Science  
Office of Research and Development

US Environmental Protection Agency  
Washington, DC 20460

202-564-6620  
[kavlock.robert@epa.gov](mailto:kavlock.robert@epa.gov)